

Application No.: 10/009,023

Docket No.: 28053/37955

REMARKS

Claims 1-10 and 26-33 are currently pending.

In the Office Action, the Examiner refers to a supplemental IDS submitted on June 10, 2004 that supposedly contained EP documents. Applicant, however, did not file a supplemental IDS on that date. Perhaps Examiner is referring to EP 0 550 060, EP 0 747 397, EP 0 846 704, and EP 0 506 166? If so, those references were submitted in the IDS mailed December 5, 2001 and were considered by the Examiner on June 13, 2003. If Examiner is referring to different EP references, Applicant kindly requests that the Examiner specify the documents to which she is referring.

I. Outstanding Rejections

Claims 1-5, 7-10, 26-28 and 30-33 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Laughlin et al., U.S. Patent No. 5,470,839.

Claims 1-10 and 26-33 stand rejected under 35 U.S.C. § 103(a) over Laughlin in view of Watanabe, U.S. Patent 5,300,311 and Garg, American Journal of Clinical Nutrition, 1998.

II. Applicants' Invention

The inventors have shown that consumption of a diet high in resistant starch and unsaturated fats or lipids results in desirable effects on carbohydrate and fat metabolism. In particular, the inventors have shown beneficial results resulting from diets which replace at least 10% of an individual's daily carbohydrate intake with resistant starch and at least 10% of the individual's saturated fat intake with unsaturated fat.

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III. Patentability Arguments**A. The Rejection Under 35 U.S.C. §102(b) over Laughlin et al. Should be Withdrawn.**

The anticipation rejection over the dietary formulation of Laughlin should be withdrawn because Laughlin fails to disclose replacement of "at least 10% of an individual's daily carbohydrate intake with resistant starch." While Laughlin teaches a dietary formulation comprising 23g of high amylose starch (which high amylose starch comprised 23% (23g/100g) of the formulation's carbohydrates), only a small fraction of high amylose starch (7.5% to 22%) is resistant starch. (See the Declaration of Ian Brown, Ph.D.) Because Laughlin fails to disclose a diet in which resistant starch would exceed 5% (i.e., $23\% \times 22\% = 5\%$), it cannot anticipate Applicants' claims.

The Examiner maintains that the claim term "resistant starch" should be given an interpretation such that the term includes starch comprising both resistant starch and non-resistant starch. As discussed below, those of skill in the art would not interpret the term as such. Because the anticipation rejection is based on a misinterpretation of the claim scope and, when given the scope that those of skill in the art would give them, the claims do not "read upon" the methods disclosed in Laughlin, the rejection should be withdrawn.

While the Examiner is obliged to examine the claims based upon their "broadest reasonable interpretation," the Examiner's interpretation must be consistent with the specification as it would be interpreted by one of skill in the art. MPEP § 2111 citing *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). In particular, the claims at issue specify percentages or grams of resistant starch. The Examiner's interpretation of "resistant starch" in the context of amounts or percentages is inconsistent with the specification. The application refers to resistant starch content (e.g., page 3, lines

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18-22) and methods of increasing the resistant starch content in starch (page 6, lines 12-13). Moreover, the application specifies on page 8, lines 3-5, that "[t]he amount of resistant starch can be demonstratd [sic] by the resistance of the starch granule or starch derived material to attack by amylases, irrespective of its amylose content." (emphasis supplied) Thus, the Examiner's position that the amounts and percentages of resistant starch recited in the claims measure the total quantity of starch is unreasonable because it is contrary to the direct teachings of the specification that amounts refer to indigestible portions of the starch "irrespective of amylose content."

Moreover, those of skill in the art, in light of the specification, would not assign the colloquial meaning of the term "resistant starch" ascribed by the Examiner to the claims. The Federal Circuit Court of Appeals recognizes that, while technical language may be used colloquially, the technical meaning of a term should be applied where those of skill in the art assign a technical meaning to a term. Application of John P. Mahony, 421 F.2d 742 (C.C.P.A. 1970). ("No one in the art would give these terms their general colloquial meaning when discussing technical matters to other persons skilled in the art." *Id.* at 746.)

Here, the Examiner ascribes a colloquial meaning of the term "resistant starch" to cover all of a starch composition only a portion of which is indigestible (resistant). Applicant argues that the amounts and percentages recited in the claims would clearly be understood by those of skill in the art to refer only to the portion of starch that is indigestible. In support, Applicant supplied the Declaration of Dr. Ian Brown which stated that "[t]hose of skill in the art of starch chemistry would recognize that a reference to 'resistant starch' in conjunction with quantitative terms such as percentages... or weights... in the claims would refer to that portion of the starch which is resistant and not to the non-resistant starch portion of the starch." Because those of skill in the art would not give the claim term "resistant starch" the

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colloquial meaning ascribed by the Examiner, the Examiner's interpretation of the term is unreasonable.

In response to the Applicant's evidence that the use of the term "resistant starch" in conjunction with a percentage or weight would invariably be understood to refer to the resistant starch portion of that starch, the Examiner merely concludes that she "can envision cases where this is true but respectfully disagrees that this is the case in all instances." This conclusory statement by the Examiner fails to rebut the explanation provided by Dr. Brown's Declaration as to why one of skill in art would invariably interpret "resistant starch" in the context of quantitative terms as the portion of starch that is resistant to digestion. When factual evidence is provided by a Declaration, the Examiner cannot reject that evidence with conclusory statements but must provide adequate reason to rebut the declaration. In re Alton, 76 F.3d 1168, (Fed. Cir. 1996). In the absence of some supporting evidence or reasoning, the Examiner's rejection of Dr. Brown's Declaration is erroneous.

Under the proper interpretation of the term "resistant starch," the anticipation rejection over Laughlin U.S. Patent No. 5,470,839 should be withdrawn because Laughlin fails to disclose replacement of "at least 10% of an individual's daily carbohydrate intake with resistant starch."

B. The Rejection Under 35 U.S.C. §103(a) over Laughlin et al. in View of Watanabe and Garg Should be Withdrawn.

The obviousness rejection over Laughlin in combination with Watanabe and Garg should also be withdrawn. Laughlin fails to disclose a diet replacing at least 10% of an individual's carbohydrate intake with resistant starch. In fact, when Laughlin discloses using 23g of high amylose starch (see the first Example Table), this provides no more than 5 grams of resistant starch when the high amylose starch is 80% amylose, which has a maximum of

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22% resistant starch. (Laughlin actually only teaches high amylose starch that is 25% to 75% amylose which have even lower resistant starch contents.) Moreover, Laughlin fails to suggest levels of resistant starch higher than 5% in its formulations. While, Laughlin discloses using high amylose starch it does not teach doing so at a level that would result in replacing at least 10% of an individual's carbohydrate intake with resistant starch. While Laughlin acknowledges that high amylose starch contains resistant starch it does not address the issue of the variability in the proportions of high amylose starch that is resistant. Without such discussion, it is clear that Laughlin is not concerned with the proportions of starch which are resistant. Thus, Laughlin fails to recognize the importance of the resistant starch content of the high amylose starch and the advantages provided by using resistant starch according to Applicants' invention.

Neither Watanabe nor Garg, make up for the deficiencies of Laughlin with respect to independent claim 1 of the applications. Watanabe is directed to a method of modifying wheat flour as an alternative to high amylose maize (amylomaze starch) because of problems with regard to its taste and texture. (see col. 1, lines 49-56) In this manner, Watanabe teaches away from elevating the content of high amylose maize in compositions such as Laughlin's and would not lead one to modify Laughlin to arrive at the claimed invention.

Garg also fails to make up for the deficiencies of Laughlin in making the claimed invention obvious. Garg provides a contrasting comparison between a high-carbohydrate diet and a monounsaturated diet. Garg finds that compared with high-carbohydrate diets, high monounsaturated fat diets improve lipoprotein profiles as well as the glycemic profile (see page 581, col. 2, lines 26-28) and concludes that a diet rich in cis-monounsaturated fats may be advantageous for improving lipoprotein and glycemic profiles in patients with diabetes mellitus (see page 581, col. 2, lines 45-47). Garg does not disclose or suggest a diet

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comprising resistant starch and does not suggest that a diet high in monounsaturated fats should be combined with any other diet. For this reason, Garg fails to make up for the deficiencies of Laughlin with respect to independent claim 1.

In addition, the obviousness rejections of claims 6 and 29 directed to treating individuals suffering from obesity should be withdrawn because Noakes et al., *The American Journal of Clinical Nutrition*, Vol. 64, pages 944-951 (1996) discussed in the previous Office Action and the response filed October 17, 2003 teaches away from replacing carbohydrates with resistant starch in diets for hypertriglyceridemic subjects who are overweight. As discussed previously, Noakes et al. teach that replacing carbohydrates with resistant starch in a diet: 1) showed no benefit in insulin sensitivity or plasma lipid responses, 2) caused dyslipidemia to worsen, and 3) accentuated the risk of coronary artery disease. This teaches away from Applicants' discovery that replacing carbohydrates and lowering fats in a diet has the benefits of a) reducing plasma leptin concentrations, b) lowering the incidence or risk of non-insulin dependent diabetes mellitus, and c) reducing post-prandial glucose and/or insulin levels.

Specifically, Noakes et al. teach that replacing as much as 25% of an overweight hyperglyceridemic subject's daily carbohydrate intake with resistant starch does not have a positive metabolic effect on plasma lipids and that replacing as much as 33% had only a small reduction in plasma insulin concentrations. (See page 8, third paragraph). In addition, Noakes et al. suggest that such replacements in combination with changes in fat intake can cause dyslipidemia to worsen. Specifically, Noakes et al. teach that:

"other studies that have made similar dietary changes in carbohydrate and fat (8,9) or fibre separately have not shown any benefit in insulin sensitivity or plasma lipid responses and in fact, dyslipidemia has been shown to worsen."

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(See Abstract, Lines 15-18).

Accordingly, the cited references fail to teach that replacing as little as 5% of an individual's daily carbohydrate with resistant starch in combination with replacing at least 10% of an individual's saturated fat intake with unsaturated fat would be successful in achieving the health benefits recited in the claims of the present invention. Accordingly, the rejections over Laughlin et al., either alone or in combination with Watanabe and Garg should be withdrawn and each of claims 1-10 and 26-33 should be allowed.

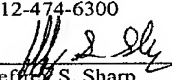
CONCLUSION

For all of the foregoing reasons, the final rejection should now be withdrawn and an notice of allowance of all pending claims is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, she is invited to contact the undersigned attorney at the number indicated below.

Respectfully submitted,

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